UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 12, 2013

Mr. Wang Ying
Director General
International Cooperation Department
Ministry of Agriculture (MoA)

Re: Food Safety Clearances in the United States for Potassium Phosphite and Fosetyl-Aluminum

Mr. Wang:

I wish to apprise you of the current status of food safety clearances for the pesticide substances potassium phosphite and fosetyl-aluminum. Please be advised that in the United States there is an exemption from the requirement of a tolerance for the potassium salts of phosphorus, and there is a tolerance (MRL) of 5 parts per million for the pesticide active ingredient fosetyl-aluminum on citrus fruit.

On Thursday, April 11th, the United States Department of Agriculture's Foreign Agriculture Service informed the EPA's Office of Pesticide Programs that the pathogen *Phytophthora syringae* (*P. syringae*) had been detected in six separate shipments of California citrus during the months of January and February 2013. *P. syringae* is one of four causal organisms that produce brown rot on citrus fruit. We understand that the presence of *P. syringae,* which is a quarantine pest in China, can result in citrus fruit not being allowed into the Chinese market. To prevent contamination of citrus with *P. syringae* in the United States, citrus is treated with either potassium phosphite as a preharvest or postharvest treatment, or fosetyl-aluminum (Aliiete®) as a preharvest treatment.

In the United States, the potassium salts of phosphorus (including potassium phosphite) are exempt from tolerance when used on all food commodities. 40 CFR 180.1210 states that "An exemption from the requirement of a tolerance is established for residues of phosphorous acid and its ammonium, sodium, and potassium salts in or on all food commodities when used as an agricultural fungicide and in or on potatoes when applied as a post-harvest treatment at 35,600 ppm or less phosphorous acid."

In the United States, fosetyl-aluminum has a tolerance (MRL) of 5 parts per million. 40 CFR 180.415 (a) states that "Tolerances are established for residues of the fungicide aluminum tris (O-ethylphosphonate), including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only aluminum tris (O-ethylphosphonate), in or on the commodity." The referenced table can be found online at http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=7be666fcd4c0191c60deb2d38c0beaf1&n=40y25.0.1.1.28&r=PART&ty=HTML#40:25.0.1.1.28.3.19.156

Should you have any further questions, please contact Nicole Berckes, Communications and Registration Liaison for Biopesticides and Pollution Prevention, at berckes.nicole@epa.gov or +1 703-308-0152.

Keith A. Matthews
Director
Biopesticides and Pollution Prevention Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 25, 2013

Mr. Wang Ying
Director General
International Cooperation Department
Ministry of Agriculture (MoA)

Re: Tolerance Exemption for Phosphorous Acid and its Ammonium, Sodium, and Potassium Salts

Mr. Wang:

I wish to provide you with information on the tolerance exemption for phosphorous acid and its ammonium, sodium, and potassium salts. Potassium phosphite is a phosphorous acid and its potassium salt.

On Thursday, April 11th, the United States Department of Agriculture's Foreign Agriculture Service informed the EPA's Office of Pesticide Programs that the pathogen *Phytophthora Syringae* (*P. syringae*) had been detected in six separate shipments of California citrus fruits during the months of January and February 2013. *P. syringae* is one of four casual organisms that produce brown rot on citrus fruit. We understand the presence of *P. syringae*, which is a quarantine pest in China, can result in citrus fruit not being allowed into the Chinese market. To prevent contamination of citrus with *P. syringae* in the United States, Citrus is treated with either potassium phosphite as a preharvest or postharvest treatment, or fosetyl-Aluminum as a Preharvest treatment. This letter summarizes the process by which the Agency determined that residues of Phosphorous acid and its ammonium, sodium, and potassium salts are exempt from the requirement of a tolerance in or all food commodities to allow for post-harvest application to stored potatoes at 35,600 parts per million (ppm) or less of phosphorus acid.

Section 408(c)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FFDCA) allows the US Environmental Protection Agency (EPA) to establish or leave in effect an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe. The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

Summary Information In Support of Tolerance Exemption for Phosphorous Acid and its Ammonium, Sodium, and Potassium Salts

71 FR 49373 is the Federal Register notice which details the tolerance exemption for phosphorous acid and its ammonium, sodium, and potassium salts. Section III: Toxicological Profile states:

> The toxicity profile for phosphorous acid and its ammonium, potassium and sodium salts has already been assessed for its pesticidal use by the Agency and published in support of the tolerance exemption for residues of phosphorous acid in or on all food commodities when used as an agricultural fungicide. See 65 FR 59346 (October 5, 2000). For the purposes of this tolerance exemption amendment, the Agency has relied on the data and/or information previously submitted and has reassessed that data in order to evaluate the request to add post-harvest uses to the tolerance exemption. Additionally, the Agency has reviewed publicly available data and information on phosphoric acid, which is chemically and structurally similar to phosphorous acid. The Agency believes that in combination, the data and other information relied upon for this tolerance exemption supports its conclusion that there is reasonable certainty of no harm that will result from the post-harvest treatment of potatoes with phosphorous acid when used according to the recommended application rate.

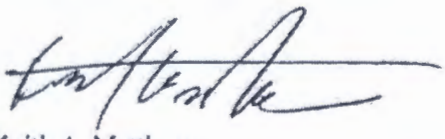
Section IV: Aggregate Exposures A. Dietary Exposure states:

> The primary issue for adding postharvest applications to a tolerance exemption is whether such application causes any new exposure that would not be safe. In order to evaluate that issue, the Agency relied on the existing toxicology data already reviewed on phosphorous acid to conduct a conservative dietary exposure and risk assessment to evaluate any additional risk that might result from post-harvest application of this chemical. In the absence of acute oral studies and any magnitude of residue data, the Agency based it's risk assessment on default assumptions, (i.e. information from the inhalation data base was used to compare to dietary risks, a common approach in the Agency), to ensure that the maximum application rates will not result in unacceptable dietary risks. As a result of this risk assessment, the Agency concludes that the use of phosphorous acid as a post-harvest treatment to stored potatoes at the recommended application rate will not add any new exposures or risks and is considered safe.

This exemption from the requirement of a tolerance and dietary risk assessment focus on postharvest applications to potatoes. However, the conclusions are directly applicable to citrus.

The full text of 71 FR 49373 is available at:
https://www.federalregister.gov/articles/2006/08/23/E6-13954/phosphorous-acid-exemption-from-the-requirement-of-a-tolerance

Should you have any further questions, please contact Nicole Berckes, Communications and Registration Liaison for Biopesticides and Pollution Prevention, at berckes.nicole@epa.gov or +1 703-308-0152.



Keith A. Matthews
Director
Biopesticides and Pollution Prevention Division